K012277

FEB 1 1 2002

510(k) SUMMARY

The Summary of Safety and Effectiveness on the Portex Ring Pessary reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies may require alterations of the conclusions or recommendations set forth.

Applicant	Claire Mullins SIMS Registration Manager SIMS Portex Ltd Hythe Kent CT21 6JL UK
Telephone	44 1303 260551
Facsimile	44 1303 266761
Date	12th July 2001
Name	Portex Ring Pessary
Classification	Class II device with Product Code 85 HHW
Predicate	PelvXGellhorn Vaginal Pessary K002329
Description	A ring pessary made from PVC or Polythene, available in various sizes, designed to ease uterine prolapse, and provide vaginal support to prevent the uterus from decending
Intended Use	Portex Ring Pessaries provide vaginal support to prevent the uterus from descending. Designed to ease uterine prolapse. Ring Pessaries are also used to correct other uterine displacements and to alleviate stress incontinence by pressure through the anterior vaginal wall onto the urethra..
Contraindications	**(PRECAUTIONS)** Inspection of the vagina using a speculum is recommended prior to insertion or replacement of a ring pessary. Ring Pessaries should be removed and reinserted as prescribed by the attending clinician. The Portex ring Pessaries are supplied non-sterile and are reusable for single patient use. Re-use of this device in another patient may result in cross infection.
Caution	**(WARNINGS)** Insertion and removal of Ring Pessaries should only be performed by competent trained personnel. After removal of Ring Pessary an inspection of the vagina should be performed to check for ulceration, bleeding, infection. Ring Pessaries should be removed and checked as prescribed by competent trained personnel to prevent embedding in the vaginal tissue or fisula formation.
Technological Characteristics	There are no published standards for these particular types of products, and as such tests have been developed which are considered sufficient to ensure the efficacy and safety of the device(s) for its intended use. Such tests include – Visual and Dimensional
Data Submitted	The biological safety assessment of the Wallace Endometrial has been performed in accordance with the International Standard ISO 10993, Part 1:1994, "Biological Evaluation of medical Devices: Evaluation and Testing." In addition to ISO 10993 the selection of tests, taking into consideration the particular application of the product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2002

Mr. Steven Ogilvie
Director, Regulatory Affairs
and Scientific Affairs
Sims Portex Limited
Hythe, Kent CT21 6JL
UNITED KINGDOM

Re: K012277
Trade/Device Name: Sim's Portex Vaginal Ring Pessary
Regulation Number: 21 CFR 884.3575
Regulation Name: Vaginal pessary
Regulatory Class: II
Product Code: 85 HHW
Dated: November 7, 2001
Received: November 13, 2001

Dear Mr. Ogilvie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K012277

Device Name: Sim's Portex Ring Pessary

Indications For Use:

Portex Ring Pessaries provide vaginal support to prevent the uterus from descending. Designed to ease uterine prolapse. Ring Pessaries are also used to correct other uterine displacements and to alleviate stress incontinence by pressure through the anterior vaginal wall onto the urethra.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓

(Optional Format 3-10-98)

Nancy C. Brogden

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012277